REMARKS

Claims 1, 4-6, 9-14, 17, 25, 26, 28, 29, 31-33 and 39 were under examination as of the issuance of the Office Action. Claims 1, 4-6, 9-14, 17, 25, 26, 28, 29, 31-33 and 39 stand rejected. In the Amendment to the Claims spanning pages 2 to 5 of this paper, claims 1, 4, 9, 10, 12, 13, 17 and 39 have been amended, claims 5 and 6 have been canceled, without prejudice, and claim 40 has been added. Accordingly, upon entry of the amendments presented herein, claims 1, 4, 9-14, 17, 25, 26, 28, 29, 31-33, 39 and 40 will remain pending in this application.

Claim 1 has been amended to include the nucleic acid molecules of claims 4 and 6, and further, to specify that these nucleic acid molecules comprise less than about 5 kb of nucleotide sequences which naturally flank the nucleotide sequence of SEQ ID NO:1 or the nucleotide sequence which encodes SEQ ID NO:2. Support for this amendment may be found throughout the specification, for example, at page 23, lines 2-8, and in the claims as originally filed, for example, claims 4 and 6. Claim 4 has been amended to include the nucleic acid molecules of claims 1 and 6, and further to specify that these nucleic acid molecules encode only polypeptides having 6-phosphogluconolactonase activity. Support for this amendment may be found throughout the specification, for example, on the first page of Table 1, and in the claims as originally filed, for example, claims 1 and 6. Claims 12 and 13 have been amended to clarify the subject matter of the claims, as suggested by the Examiner. Claim 39 has been amended to recite a sequence of at least 97% identity to the nucleotide sequence of SEQ ID NO:1. Support for the amendment to claim 39 may be found throughout the specification, for example, at page 4, line 32 to page 5, line 10.

No new matter has been added by these claim amendments or by the introduction of the new claim. Any cancellation and/or amendments to the claims have been made solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner's rejections. Applicants reserve the right to pursue the claims as originally filed in one or more further applications.

Withdrawn Claim Rejections/ Objections

Applicants gratefully acknowledge the Examiner's withdrawal of the following rejections and objections:

a) objection to claim 27 under 37 C.F.R. §1.75 as being in improper dependent form;

b) objection to claim 33 as containing improper Markush language; and

c) rejection of claims 1, 5 and 6 under 35 U.S.C. § 112, second paragraph, as being indefinite for use of phrases "a complement thereof" and "the complement of a nucleic acid molecule consisting of SEQ ID NO:1".

Priority

Applicants acknowledge that the instant claims are granted the priority date of June 23, 2000, the filing date of the instant application. Additionally, Applicants note that certified copies of the foreign German patent applications will be filed upon issuance of a patent, upon which Applicants request grant of foreign priority.

Rejection of Claims 12-14 Under 35 U.S.C. § 101

The Examiner has rejected claims 12-14 under 35 U.S.C. § 101, as being directed to non-statutory subject matter. In particular, the Examiner is of the opinion that

> [c]laim 12, as written, encompass [sic] naturally occurring whole organisms including humans, animals, plants as well as transgenic humans, animals, plants, all of which are non-statutory subject matter. (Office Action, page 3)

In the interest of expediting examination and in accordance with the Examiner's suggestion, Applicants have amended claim 12, without prejudice, such that it is now directed to "[a]n isolated host cell...". In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 12-14 under 35 U.S.C. § 101.

Rejection of Claims 5, 6, 9-14, 17 and 39 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 5, 6, 9-14, 17 and 39 under 35 U.S.C. § 112, first paragraph as not being sufficiently enabled. In particular, the Examiner is of the opinion that

> ...Example 14 of the Written Description Guidelines cannot be used in evaluating the instant claims for compliance with the enablement requirement of 35 U.S.C. 112, first paragraph. A separate analysis is required to determine whether the specification enables one skilled in the art to make and[/]or use the claimed invention without undue experimentation. (Office Action, page 4)

Applicants traverse the foregoing rejection as it pertains to previously numbered claim 6 (the subject matter of which has now been incorporated into claims 1 and 4, as amended), and claims depending therefrom, for the following reasons. Applicants submit that, even though Example 14 is part of the *Written Description Guidelines* and not the *Enablement Guidelines*, it does state explicitly that ***one skilled in the art would be able to generate a nucleotide sequence of 95% identity to another nucleotide sequence using only routine experimentation***. Specifically, the relevant section of Example 14 provides that "*[t]he procedures for making variants of SEQ ID NO:3* ***are conventional in the art*** *and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are* ***conventional in the art***" **(emphasis added)**.

Accordingly, while the *Written Description Guidelines* are generally directed to describing the standard for satisfying the written description requirement, in this particular example, the Guidelines clearly provide guidance on the USPTO's position regarding a key question for determining whether the enablement requirement has been satisfied: would it be routine for one of skill in the art to generate a sequence with 95% identity to a specified nucleotide sequence and which retains the activity of that specified nucleotide sequence? The answer to that question, as provided by the USPTO, is: yes. The Guidelines provide that claims to sequences of 95% identity with a functional limitation are sufficiently enabled where the specification provides assays for the identification of such sequences having the requisite function. Accordingly, because it is conventional, *i.e.*, routine, to make sequences of at least 95% identity and because the instant specification provides assays for identifying nucleic acid sequences of SEQ ID NO:1 that encode for a polypeptide having 6-phosphogluconolactonase activity (see, for example, Examples 4-8 on page 51, line 29 through page 56, line 28 of the specification), one of skill in the art would be able to make and use the claimed invention using only routine experimentation. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 4, 9-14, 17 and 39 under 35 U.S.C. § 112, first paragraph.

In the interest of expediting examination and in no way acquiescing to the validity of the Examiner's rejections, Applicants have cancelled claim 5 without prejudice, thereby rendering the rejection of claim 5 moot.

Rejection of Claims 1, 4-6, 9-14, 17, 25-29, 31-33 and 39 Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1, 4-6, 9-14, 17, 25-29, 31-33 and 39 under 35 U.S.C. §102(e) as being anticipated by Dunican *et al.* (USPN 6,797,509) (hereinafter referred to as "Dunican"). In particular, the Examiner is of the opinion that

> Dunican et al. teach a 6995 base pair DNA sequence... that is 100% identical to SEQ ID NO:1 of the claimed invention... The Examiner takes the position that in absence of facts to the contrary the DNA taught by Dunican et al. would inherently encode a polypeptide having 6-phosphogluconolactonase activity since Dunican et al. teach a 6995 base pair DNA sequence that is 100% identical to SEQ ID NO:1 of the claimed invention. (Office Action, page 6)

Applicants traverse the foregoing rejection for the following reasons. Claims 1 and 4, as amended, are directed to nucleic acid molecules comprising SEQ ID NO:1 or encoding a polypeptide comprising SEQ ID NO:2, where either (a) the nucleic acid molecule includes less than about 5 kb of nucleotide sequences which naturally flank the nucleotide sequence of SEQ ID NO:1; or (b) the nucleic acid molecule encodes only a polypeptide having 6-phosphogluconolactonase activity.

For a prior art reference to anticipate, in terms of 35 U.S.C. § 102, a claimed invention, the prior art must teach each and every element of the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987). Applicants respectfully submit that Dunican fails to teach or suggest all the elements of the claims, as amended. Specifically, Dunican fails to teach or suggest nucleic acid molecules comprising SEQ ID NO:1 or encoding a polypeptide comprising SEQ ID NO:2, where the nucleic acid molecule includes less than about 5 kb of nucleotide sequences which naturally flank the nucleotide sequence of SEQ ID NO:1 or the nucleotide sequence encoding SEQ ID NO:2, as required by claim 1. Indeed, as demonstrated in Appendix A, enclosed herewith, Dunican discloses a nucleic acid molecule in which the nucleotide sequence shared with the present invention is

flanked by over 6 kb of naturally present nucleotide sequences on the 3' region alone. Accordingly, Dunican fails to teach each and every element of claim 1, and claims dependent therefrom.

Additionally, Dunican fails to teach or suggest nucleic acid molecules comprising SEQ ID NO:1 or encoding a polypeptide comprising SEQ ID NO:2, where the nucleic acid molecule encodes ***only*** a polypeptide having 6-phosphogluconolactonase activity, as required by claim 4. Indeed if one were to express the nucleic acid molecule of Dunican, as suggested by the Examiner, the nucleic acid molecule would encode at least two polypeptides, one of which would have transaldolase activity. Accordingly, Dunican fails to teach each and every element of claim 4, and claims depending therefrom.

In view of all of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 102(e).

CONCLUSION

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested. If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

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Respectfully submitted,

By _____

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